

### Remarks

#### A. *Status of Claims*

Claims 21-30 remain pending. No claim amendments are being presented. No new matter has been added.

#### B. *Section 102 Rejection*

Claims 21-23, 27, and 30 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,658,575 to Ribier *et al.* Applicants respectfully traverse.

The underlying basis for the claims rejections is erroneous. Claims must be given their plain meaning *unless* applicant has provided a clear definition in the Specification. *In re Zletz*, 893 F.2d 319, 321, 12 USPQ2d 1320, 12, 22 (Fed. Cir. 1989) and MPEP 2111.01. When the Specification provides definitions for terms appearing in the claims, the Specification can be used in interpreting claim language. *In re Vogel*, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970); MPEP §2111.01.

The Examiner has incorrectly characterized claims of the present invention by not considering explicit definitions provided in the Specification. For example, the Examiner argues that the only difference between an emulsion and a microemulsion is a co-surfactant. *See* Office Action, page 5. The Examiner has failed to provide proof to support this conclusion. If the Examiner is relying upon personal knowledge, no affidavit has been provided. MPEP §2144.03 (setting forth the requirements of reliance of common knowledge in the art).

Claim 21 recites a method of making a nanoparticle that includes “making an oil-in water microemulsion.” The term “microemulsion” is defined in the Specification beginning on page 12, line 25, which states:

a “microemulsion” is a stable biphasic mixture of two immiscible liquids stabilized by a surfactant and usually a co-surfactant. Microemulsions are thermodynamically stable, isotropically clear, form spontaneously without excessive mixing, and have dispersed droplets in the range of about 5 nm to 140 nm.

The Examiner did not take this explicit definition into account and erroneously concluded that Ribier’s disclosure of an *emulsion* is equivalent to a microemulsion of the present application. However, the *emulsion* of Ribier is obtained when an oily phase and an aqueous phase are combined and stirred at 4000 rev/min provided by a Moritz homogenizer of type Turbo Lab 2100 and the stirring conditions are maintained for 30 minutes. See Ribier, column 6, lines 53-61. This extensive mixing process of the cited reference is clearly different from the microemulsions formed “spontaneously without excessive mixing” as defined in the present Specification. Furthermore, Ribier appears to support the present Specification’s definition of an emulsion. For example, the Specification defines emulsions as:

usually require the application of high-torque mechanical mixing or homogenization to produce dispersed droplets in the range of about 0.2 to 25  $\mu\text{m}$ . See page 12, lines 29-31.

Independent claim 21 and its dependent claims require a *microemulsion* set forth and defined in the Specification. Such a microemulsion is clearly absent from Ribier. For at least this reason, independent claim 21 and its dependent claims are patentably distinct over Ribier.

Additionally, Ribier fails to anticipate or suggest the step of cooling a microemulsion to form a nanoparticle, as recited by claim 21. The Specification defines the term nanoparticle beginning on page 12, line 14, which states:

[t]he term “nanoparticle” refers to particles that have diameters below 1 micrometer in diameter that are comprised of primarily one solid phase...The solid nanoparticles may contain, or have adsorbed to, many different materials for various pharmaceutical and engineering applications such as plasmid DNA for gene therapy and genetic vaccines, peptides and proteins or small drug molecules, magnetic substances for use as nanomagnets, lubricants, or chemical, thermal, or biological sensors

In contrast, Ribier discloses that an emulsion and oily globules are generated after the mixing of an oily phase and an aqueous phase. *See* Ribier, column 6, lines 49-64. In Ribier, the active agent of a compound is “contained in or constituted by the oily globule [and] may consequently be transported and delivered to the skin or hair at the site where its action will be the most effective.” *See* Ribier, column 3, lines 25-28. As such, Ribier produces the intended compound (Examples 1-15) during the mixing of an oil phase and an aqueous phase. Any subsequent cooling of the emulsion to room temperature after the mixing process does not produce a nanoparticle, especially a “nanoparticle” as defined in the present Specification.

Moreover, Ribier does not anticipate or even suggest cooling a microemulsion to form a nanoparticle. Ribier discloses that a compound may be incorporated into pre-existing particles. *See* Ribier, column 5, lines 34-38 (disclosing the incorporation of the compositions into pre-existing nanospheres, nanosponges, or nanocapsules). The incorporation of compounds into particles can not be construed as cooling a microemulsion to form a “nanoparticle” as required by claim 21 and defined by the Specification.

For at least these reasons, Ribier fails to anticipate or even render obvious independent claim 21 and its dependent claims. The removal of the §102 rejection is respectfully requested.

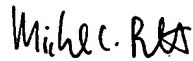
*C. Section 103 Rejections*

Dependent claims 24-26, 28, and 29 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ribier. Applicants respectfully traverse. Rejected dependent claims 24-26, 28, and 29 are in condition for allowance for at least the reasons given above with respect to independent claim 21. Namely, the cited art does not disclose or suggest explicit elements required by claim 21.

*D. Conclusion*

Applicants believe that this submission fully responds to all outstanding matters for this application. Applicants respectfully request that the rejections of all claims be withdrawn so the claims may swiftly pass to issuance. Should the Examiner desire to sustain any rejection, the courtesy of a telephonic conference between the Examiner, the Examiner's supervisor, and the undersigned attorney at 512-536-3018 is respectfully requested in advance.

Respectfully submitted,



Michael C. Barrett  
Reg. No. 44,523  
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.  
600 Congress Avenue, Suite 2400  
Austin, Texas 78701  
Telephone: 512-536-3018  
Facsimile: 512-536-4598

Date: June 4, 2004